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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,088	01/21/2000	Sung-Yun Kwon	7010-0014	5348

7590 05/20/2002
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EXAMINER

GHALI, ISIS A D

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/20/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489,088

Applicant(s)

Kown et al.

Examiner

Isis Ghali

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– Th MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 6, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) 33-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 8 6) ☐ Other:

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DETAILED ACTION

The receipt is acknowledged of applicants' IDS, filed 1/16/2001; request for extension of time, request for reconsideration, and IDS, all filed 2/13/2001; request for extension of time and election, both filed 8/27/2001; change of address filed 2/20/2002; and request for extension of time and election, both filed 3/8/2002.

1. Applicant's election without traverse of Group I, claims 1-32, in Paper No. 11; and election of the species metal particles in Paper No. 15 are acknowledged.
2. Claims 33-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11.

Claims 1-32 are included in the prosecution.

Response to Arguments

3. Applicant's arguments filed 2/13/2001 have been fully considered but they are not persuasive.

The standing rejection in this application is:

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Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over '796 in view of Mak, US '477.

US '796 is teaching a needleless syringe for effective transdermal delivery of particles containing a therapeutic agent such as viruses or proteins (antigen), insulin with a carrier (adjuvant) or a placebo. Injection velocities may be between 200 up to 3000 m/sec. and the particle size ranges from 0.1 to 250 micrometer. The particles can be made from metal. The drug particles can be encapsulated. More than one therapeutic agent can be injected together. See the abstract, col.2, lines 30-37; col.4, lines 1-23, 40-55; col.8, lines 17-20; col.10, example 2.

The reference does not teach topically positioning a transdermal drug delivery device or a first occlusive dressing comprising a therapeutic agent.

However, it is obvious to one having ordinary skill in the art at the time the invention was made to dress the site of the injection with an occlusive dressing or a transdermal device after injection as a routine technique. Including a therapeutic agent in the TTS flowing logically from the transdermal delivery art.

US '477 is teaching formulation for topical administration of therapeutic agents in the form of powder such as proteins, peptides, inorganic ions (metal placebo), oligosaccharides or an antigen. Delivery device can be active or passive in the form of transdermal patch or occlusive dressing and absorption enhancer can be used. The occlusive dressing optionally applied to the skin after the therapeutic agent is applied to

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area of the skin to be treated. The reference also teach the pretreatment of area of skin upon which the drug is to be placed prior to attachment of the transdermal patch to the skin. The reference teaches the use of two separate dosage forms at the same time. See col.5, lines 1-8; col.7, lines 17-25; col.42, lines 62-65; col.43, lines 10-18, 33-34; col.46, lines 55-56; col.48, lines 18-20, 54-56; col.52, lines 25-26, 38-44; col.53, lines 2-11, 37-46; col.55, lines 23-33; col.59, lines 5-19.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the drug to the skin by the needleless syringe of '796 and then apply a transdermal device of US '477 containing the same or different drug, with reasonable expectation of the achieved method to administer drugs or combination of drugs through the skin.

Applicants argument:

- US '796 fails to teach a process that combines two disparate delivery elements in two steps to enhance therapeutic delivery device.
- US '477 does not teach the use of particle delivery system in combination with occlusion and/or transdermal delivery technique. The reference also teaches numerous drugs and numerous delivery techniques.
- No suggestion to combine the references, the only way to arrive to this combination is through the applicants' own disclosure.

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Examiner's position is:

- Claim 1 is broad and it can read on a routine drug injection followed by application of a band-aid or a dressing containing an antiseptic. Injecting the particles of US '796 is logically followed by any kind of dressing, even if not disclosed. The step of accelerating particles can read on applying a penetration enhancer or the pretreatment disclosed by US '477, or by the chemical abrasive disclosed by US 6,030,374, art of record pertinent to applicant's invention. The standing rejection is based on combination of the references, and one can not show nonobviousness by attacking the references individually. In this case it is obvious to apply a medicated dressing with any antiseptic after injecting a drug and it is also obvious to accelerate the drug delivery through the skin by applying a pretreatment with an enhancer or with a chemical abrasive. It is obvious to combine two components or steps each of which is taught by the prior art to be useful for the same purpose desired by applicants, which is accelerating the drug delivery across the skin or mucosa.
- US '796 teaches the injection of the particles with obvious dressing application followed after the injection.
- US '477 teaches transdermal administration of antigen and adjuvant preceded by treatment to the area of application to accelerate the drug delivery. The

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expression "comprising" of the claims' language permits the presence of other ingredients, active or inactive even in major amounts.

- In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the drug to the skin by the needleless syringe of '796 and then apply a transdermal device of US '477 containing the same or different drug, with reasonable expectation of the achieved method to administer drugs or combination of drugs through the skin. The motivation would arise from the logic of the transdermal art or from the teaching of US '477 that a pretreatment is applied to enhance the drug delivery. In response to applicant's argument that the only way to arrive to the applicants' combination is through the applicants' own disclosure, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into

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account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Isis Ghali whose telephone number is (703)

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305-4048. The examiner can normally be reached on Monday-Friday from 7:00 to 5:30 Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

Isis Ghali


THURMAN K. PAGE
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